without prejudice or disclaimer. Claims 21-36 are added as new claims. Support for these amendments can be found at least on pages 12-15 of the present application. Applicant respectfully submits that no new matter has been added by way of the above amendments.

Applicant has amended Claims 1 and 10 to more clearly recite a composition and method of treating HIV infected patients by administering the composition of at least one anti-HIV drug and a cortisol blocker comprising procaine HCl, zinc heptahydrate, and ascorbic acid.

I. Rejection Under 35 U.S.C. § 103

Claims 1-3, 5, 10, 11, 13, 14, 17, and 19 were rejected under 35 U.S.C. §103 as being unpatentable over Devita et al. in combination with Beale and Lemay et al. Applicant respectfully traverses the rejection and requests withdrawal of the same.

a. The Elements of Claims 1-3 and 5 are not Disclosed in the Prior Art

Claim 1 recites a pharmaceutical composition for enteral administration comprising at least one anti-HIV drug and a cortisol blocker comprising procaine HCl, zinc heptahydrate, and ascorbic acid.

Devita et al. allegedly discloses that combinations of ***anti-HIV drugs*** are beneficial in treating HIV infection. There is no mention of a cortisol blocker.

Beale allegedly teaches the use of anti-cortisol compounds such as HMB, DHEA, Ipriflavone and phosphatidylserine in the treatment of patients with AIDS to reduce the catabolic effects associated with AIDS. Beale does not teach the use of anti-cortisol compounds in a composition with anti-HIV drugs.

Lemay et al. allegedly teach the cortisol blocker ketoconazole in combination with the anti-HIV drug zidovudine (AZT).

None of the cited references, alone or in combination, teach the combination composition as recited in Claim 1. Particularly, the cited references do not teach or suggest a cortisol blocker

mixture including procaine HCl, zinc heptahydrate, and ascorbic acid. Applicant respectfully submits that Claim 1 is patentable over the cited art.

Claims 2, 3, and 5 depend from independent Claim 1 and therefore are likewise patentable over the cited art.

Claim 17 has been cancelled without prejudice or disclaimer.

b. The Elements of Claims 10, 11, 13 and 14 are not Disclosed in the Prior Art

Claim 10 recites, among other things, a method for the treatment of HIV infected patients comprising enterally administering to the patient at least one anti-HIV drug and a cortisol blocker comprising procaine HCl, zinc heptahydrate, and ascorbic acid.

None of the cited references, alone or in combination, teach the method of treating an HIV infected patient as recited in Claim 10. Particularly, the cited references do not teach or suggest administering to a patient a cortisol blocker mixture including procaine HCl, zinc heptahydrate, and ascorbic acid. Applicant respectfully submits that Claim 10 is patentable over the cited art.

Claims 11, 13, and 14 depend from independent Claim 10 and therefore are likewise patentable over the prior art.

Claim 19 has been cancelled without prejudice or disclaimer.

c. Applicant's §1.132 Declaration Reveals Unexpected Results Achieved by the Claimed Invention

The §1.132 Declaration of Dr. Vassilios Papadopoulos of Georgetown University reveals a synergistic anti-cortisol effect obtained from the combination of procaine HCl, zinc heptahydrate, and ascorbic acid. The anti-cortisol effect of the combination of drugs was extremely elevated in comparison with the anti-cortisol capabilities of each ingredient taken separately.

*d. **Establishing Prima Facie Case of Obviousness Lies with the Examiner***

It is well established that the burden of establishing a *prima facie* case of obviousness lies with the Examiner. In determining obviousness, one must focus on the invention as a whole. *Symbol Technologies Inc. v. Opticon Inc.*, 19 USPQ 2d 1241, 1246 (Fed. Cir. 1991). The primary inquiry is: "Whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success.... Both the suggestion and the expectation of success must be found in the prior art, not the applicant's disclosure." *In re Dow Chemical*, 5 USPQ 2d 1531 (Fed. Cir. 1988). When all the prior art is considered together, a person having ordinary skill in the art must have a sufficient basis for the necessary predictability of success to sustain a rejection under 35 U.S.C § 103. *See Ex parte Novitski* 26 USPQ2d 1389 (Bd.Pat.App. & Int. 1993), citing *In re Clinton*, 188 USPQ 365 (CCPA 1976).

The cited references do not teach or suggest to one of ordinary skill in the art the present claimed invention, particularly the presently claimed cortisol blocker mixture including procaine HCl, zinc heptahydrate, and ascorbic acid. There is no teaching or suggestion that the combination of procaine HCl, zinc heptahydrate, and ascorbic acid would produce a greater anti-cortisol effect than any of the components taken alone. Thus, these references do not provide one of ordinary skill in the art that the present claimed invention would have had a reasonable likelihood of success.

Again, both the suggestion and the expectation of success must be found in the prior art, not the applicant's disclosure. From the cited references, a person having ordinary skill in the art would not have a sufficient basis for the necessary predictability of success to sustain a rejection under 35 U.S.C § 103.

II. Conclusion

With entry of the above Amendment and in view of the foregoing remarks, it is respectfully submitted that claims 1-3, 5, 10, 11, 13, 14, and 21-36 are in condition for allowance.

None of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application.

Also submitted below, on a separate page titled "Version with Marking to Show Changes Made to the Claims," is a marked-up copy of prior pending claims and the specification. It is respectfully submitted in view of the foregoing Amendment and Remarks that all of the objections and rejections in the Office Action dated April 10, 2001 have been overcome and should be withdrawn. Applicant respectfully requests early and favorable notification to that effect. The Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,

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Dated: September 16, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE.

1. (Twice Amended) A composition for enteral administration comprising at least one anti-HIV drug and [at least one] a cortisol blocker comprising [selected from the group consisting of] procaine HCl, [zinc, zinc salts,] zinc heptahydrate, [lidocaine HCl, phosphatidylserine, RU-486, HMB, pregnenalone, clonidine and ipriflavone] and ascorbic acid.

10. (Thrice Amended) A method for the treatment of a human immunodeficiency virus infected patient[s], the [said] method comprising enterally administering to the patient at least one anti-HIV drug and [at least one] a cortisol blocker comprising [selected from the group consisting of] procaine HCl, [zinc, zinc salts,] zinc heptahydrate, [lidocaine HCl, phosphatidylserine, RU-486, HMB, pregnenalone, clonidine and ipriflavone] and ascorbic acid.